Claims 1, 2 and 10 are rejected for lack of Novelty under 35 USC § 102, or alternatively, for Obviousness under 35 USC § 103, based on the disclosure of Deboeck, et al. USP 5,545, 628. Claim 7 is rejected for Anticipation under 35 USC § 102 and for Obviousness under 35 USC § 103 in view of the disclosure of Barnwell, et al., USP 6,153,218. Finally, the Office combines the Barnwell, et al. disclosure with nifedipine standards prepared in Crison, et al., USP 5,993,858 to make an Obviousness rejection of Claim 7.

With this Response and Amendment, the Applicants amend generic Claim 1 to incorporate the composition limitations of Claim 3 *(i.e., compositions which include a continuous dispersing phase, a dispersed phase, and at least one active ingredient)*, thereby effectively distinguishing all claims from the cited prior art, since there are no prior art rejections of Claim 3 on record. The Applicants submit that redrafted generic Claim 1 is hereby patentably distinct in the view of the Office, and all remaining claims are dependent on Claim 1 in some manner. Therefore, reconsideration and withdrawal of the prior art rejections is respectfully solicited.

The Office also raises rejections under 35 USC § 112, first and second paragraphs, in addition to minor objections as to form.

Claims 1, 2, and 10 are rejected under 35 USC § 112, first paragraph, for lack of enablement of thixotropic compositions, in general. The Office concludes that only compositions which include a continuous dispersing phase, a dispersed phase, and at least one active ingredient are enabled by the Specification. With this Response, the Applicants have amended base Claim 1 to include the limitations of the Specificational disclosure noted above, thereby enabling Claim

1 and dependent Claims 2, and 10. Reconsideration and withdrawal of the rejection for lack of enablement are respectfully solicited.

Claims 1, 2, 4, 5, 7, and 10 are rejected under 35 USC §112, second paragraph, for indefiniteness.

The Office concludes that the phrase *"such as"* renders Claims 4 and 10 indefinite. With this Response and Amendment, the Applicants delete the phrase from Claim 4 and replace it with the language *"selected from"*, thereby rendering Claim 4 definite. Regarding Claim 10, the Applicants remove the phrase *"such as hydroxypropylmethylcellulose"* and specify the associated limitation in a new dependent claim (11).

The Office rejects Claims 5 and 7 under 35 USC § 112, second paragraph, for indefiniteness because the claim language does not involve proper "Markush" form. With this Response and Amendment, the Applicants amend the claims to replace *"chosen from"* with the language *"selected from"*. The Applicants respectfully submit that the language is acceptable Markush format according to MPEP § 2173.05(h) which states: *"When materials recited in a claim are so related to constitute a proper Markush group, they may be recited in the conventional manner, or alternatively. For examples, if "wherein R is a material* ***selected from*** *the group consisting of A, B, C, and D" is a proper limitation."* The designated phrase in Claims 5 and 7 sets forth with clarity the claim to a composition with 'ingredients' selected from the specified group, which is appropriate Markush form. Hence, the Applicants request reconsideration and withdrawal of this rejection.

The Office has not defined the basis for the indefiniteness rejection regarding Claims 1 and 2. Nevertheless, with this Response and Amendment, the Applicants remove the language *"such that"* in Claim 1 and *"characterized in that"* in Claim 2; and replace both phrases with *"wherein"*. The Applicants submit that these changes address any possible concern the Office may have regarding failure to claim with particularity in Claims 1 and 2.

The last indefiniteness rejection involves the language of Claim 10, which reads *"...gelatin or any other cellulose polymer..."*. It is the position of the Office that gelatin is not a cellulose polymer; hence, the word *"other"* should be removed from the phrase. With this Response and Amendment, the Applicants delete *"other"* from Claim 10.

The Applicants submit that the instant amendments are responsive to the Office's outstanding rejections for indefiniteness; hence, reconsideration and withdrawal of all rejections under 35 USC § 112, second paragraph, is respectfully solicited.

Finally, the Office raises several objections regarding the form of the Abstract and the Specification.

First, the Office has asked the Applicants to provide an abstract on a separate sheet. The Applicants respectfully submit that this request is improper under MPEP § 1893.03(e). According to procedure, the Office is to rely on the abstract which is printed on the cover of the PCT pamphlet. The Applicants point out that such an abstract is clearly present on the cover page of the instant application.

Second, the Office has asked the Applicants to remove the word *"other"* from the Specification at page 8, line 31. This request conforms with the rejection of Claim 10 for indefiniteness. With this Response and Amendment, the Applicants delete the offending language, thereby responding to the Office concern.

Third, the Office has asked the Applicants to insert the heading:
" - - BRIEF DESCRIPTION OF DRAWINGS - - " on page 9, between lines 3 and 4 of the Specification. With this Response and Amendment, the Applicants comply with the request by submitting an amended Specification page.

Fourth, the Office has asked the Applicants to insert language into the Specification identifying the application as a 35 USC § 371 National Phase application. The Applicants respectfully submit that this request is not required under MPEP § 1893.03(a) because the application was filed along with Form PTO-1390; which form makes of record the requested assertion that the application is a National Phase application.

The Applicants having fully responded to the Office concerns regarding form, hereby respectfully request that all objections regarding the Abstract and Specification be withdrawn.

* * * * *

Accordingly, entry of the present amendment, reconsideration of all grounds of objection and rejection, withdrawal thereof, and passage of this application to issue are all hereby respectfully solicited.

It should be apparent that the undersigned attorney has made an earnest effort to place this application into condition for immediate allowance. If he can be of assistance to the Examiner in the elimination of any possibly-outstanding insignificant impediment to an immediate allowance, the Examiner is respectfully invited to call him at his below-listed number for such purpose.

Allowance is solicited.

Respectfully submitted,

THE FIRM OF HUESCHEN AND SAGE

By: _____
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Dated: March 6, 2003
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Enclosure: Postal Card Receipt; Check No. 71479 in the amount of $930 for three (3) month extension; Amended Claims in clean and marked-up form; two (2) replacement Specification pages.

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THE COMMISSIONER IS HEREBY AUTHORIZED TO CHARGE ANY FURTHER OR ADDITIONAL FEES WHICH MAY BE REQUIRED (DUE TO OMISSION, DEFICIENCY, OR OTHERWISE), OR TO CREDIT ANY OVERPAYMENT, TO DEPOSIT ACCOUNT NO. 08,3220.

CLAIMS (MARKED-UP FORM)

1. Liquid or pasty thixotropic compositions which contain a continuous dispersing phase, a dispersed phase and [containing] one or more active substances, intended for filling hard capsules at room temperature, [such that] wherein :

   - their complex modulus G* is greater than about 100 Pa,
   - their phase shift δ is less than about 45°,
   - their viscosity decreases with increasing shear rate,
   - under the effect of a constant shear rate γ_o, the viscosity of the said compositions decreases in a delayed manner over time and stabilizes at the equilibrium value η_{eq} of between 10 mPa.s and about 10,000 mPa.s, when γ_o is between 100 and 1000 s^{-1} and
   - after making the said shear rate 0, the complex modulus and the phase shift of the said compositions resume, after a time t of less than 1 hour, G* and δ values of greater than about 100 Pa and of less than about 45°, respectively.

2. A composition according to Claim 1, [characterized in that] wherein:

   - G* is greater than 1000 Pa, and/or
   - δ is less than 25° and /or
   - η_{eq} is between 100 and 1500 mPa.s when γ_o is between 100 and 1000 s^{-1} and/or
   - t is less than 30 min.

3. [A composition according to Claim 1, which contains a continuous dispersing phase, a dispersed phase and at least one active substance.]

4. A composition according to Claim [3] 1, wherein [characterized in that] the continuous phase consists of at least one vehicle [such as] selected from amphiphilic esters having an HLB of between 3 and 15 and more particularly polyglycolized glycerides.

5. A composition according to Claim [3] 1 , wherein [characterized in that] the dispersed phase is selected from [chosen from] hydrophilic or hydrophobic pyrogenic silica particles and ethylene oxide/propylene oxide copolymers, the latter making it possible to achieve, when combined with the continuous phase, HLB values ranging up to about 20.

6. A composition according to Claim [3] 1, wherein [characterized in that] the active substance is liquid, pasty or solid.

7. A composition according to Claim 6, wherein [characterized in that] the active substance is selected from [chosen from] milnacipran hydrochloride, baquimast, nifedipine, triamterene, aluminum hydroxychloride, sodium salicylate, vancomycin, paramethadone and griseofulvin.

8. A composition according to Claim [3] 1, wherein [characterized in that] the dispersed phase of the preparations according to the invention represent 1 to 30% m/m of the preparation.

9. A composition according to Claim 8, wherein [characterized in that] the dispersed phase of the dispersions according to the invention represent from 5 to 15% m/m of the preparation.

10. A composition according to Claim 1, wherein [characterized in that] the hard capsules consist of gelatin or of any [other] cellulose polymer capable of fulfilling the functions of the use of gelatin in the form of a hard capsule [, such as hydroxypropylmethylcellulose].

11. A composition according to Claim 1, wherein the hard capsules consist of hydroxypropylmethylcellulose.